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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/008,945	01/20/98	GRIFFITH-CIMA	L 20220-0169

EXAMINER
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HM22/0817

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NAFF-P ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/17/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/22/99

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-9, 11, 12 + 14-22 is/are pending in the application.  
☐ Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1-9, 11, 12 + 14-22 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12 (filed 7/22/99)  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

The request filed on 7/22/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/008,945 is acceptable and a CPA has been established. An action on the CPA follows.

The preliminary amendment of 7/22/99 has been entered. The  
5 amendment amended the specification and claims 1-9, 11, 12 and 14-18, canceled claims 10 and 13, and added claims 19-22.

Claims examined on the merits are 1-9, 11, 12 and 14-22 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in  
10 this action can be found in a prior Office action.

The Vacanti et al document from J. Ped. Surg. listed on form PTO-1449 of 6/22/99 has been lined through and not considered since a copy of the document did not accompany the form and a copy of the document was not supplied in parent application 08/056,140. The references listed on  
15 U.S. Patent No. 5,709,854 that issued from the parent application do not include Vacanti et al as a reference that was considered.

Claims 11, 12, 14-18, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as  
20 the invention.

The claims are confusing and unclear by designating a cell-polymeric composition as a medical device in claim 11. A composition is not a device.

Dependent claims 12 and 14-18 are confusing and unclear by reciting  
25 "The composition of claim 11" since claim 11 is claiming a device.

Dependent claims 21 and 22 are confusing and unclear by reciting "The method of claim 18" since claim 18 is drawn to a composition.

Claims 11, 12, 14-18, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no description in the specification of a cell-polymeric composition forming a medical device as required in claim 11.

Claims 1, 3-8, 11 and 14-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Atala et al (Journal of Urology) (presented at annual meeting on Oct. 10-15, 1992).

The claims are drawn to a method and composition wherein a hydrogel solution containing cells is formed and the solution is implanted to form tissue *in vivo*.

Atala et al disclose preparing an injectable alginate solution containing cells and injecting the solution to form tissue *in vivo*.

Claims 2, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala et al in view of Nevo et al (4,642,120) and Vacanti et al (5,041,138).

It would have been obvious to gel the alginate solution containing cells of Atala et al in a mold to provide a desired shape, and then implant the shaped gel as suggested by Nevo et al implanting a gel containing cells to repair a defect and Vacanti et al implanting a cell-containing matrix having a desired shape to form shaped new tissue.

Claims 1, 3-8, 11 and 14-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,709,854 or claims 1-19 of U.S. Patent No. 5,667,778. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the patents require producing a hydrogel solution containing cells and injecting the solution to form tissue *in vivo*, and make obvious the formation and implanting of a hydrogel solution containing cells to form tissue as presently claimed.

Claims 2, 9 and 12 are rejected on obvious double patenting as set forth above over the claims of the patents in further view of Nevo et al and Vacanti et al.

It would have been obvious to gel the hydrogel gel solution containing cells of the patent claims in a mold to provide a desired shape, and then implant the shaped gel as suggested by Nevo et al implanting a gel containing cells to repair a defect and Vacanti et al implanting a shaped matrix containing cells to form shaped new tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

Serial Number: 09/008,945  
Art Unit: 1651

Page 5


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 305-3014 or 308-4242.

5 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN  
8/16/99

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128  
(105)